**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF WEST VIRGINIA**
**AT CHARLESTON**

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| **IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION**<br><br>**THIS DOCUMENT RELATES TO: ALL WAVE 3 CASES**[1] | **Master File No. 2:12-MD-02327**<br>**MDL No. 2327**<br><br>**JOSEPH R. GOODWIN**<br>**U.S. DISTRICT JUDGE** |

**RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE THE TESTIMONY OF HARRY JOHNSON, M.D.**

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon") submit this response in opposition to Plaintiffs' Motion to Exclude the Opinions and Testimony of Harry Johnson, M.D. ("Plaintiffs' Motion") [Dkt. 3273].

## INTRODUCTION

Dr. Johnson is a board-certified urogynecologist with more than three decades of experience in the field. Ethicon designated Dr. Johnson to offer both general and case-specific opinions. Plaintiffs' Motion [Dkt. 3273] concerns only Dr. Johnson's general opinion testimony.

As an initial matter, Plaintiffs challenge neither Dr. Johnson's qualification nor his methodology in relation to the vast majority of his proffered opinions. Plaintiffs' silence in this regard is a testament to Dr. Johnson's credentials and the reliability of his methodology. Instead, Plaintiffs challenge six discrete opinions from Dr. Johnson's report. Plaintiffs challenge two opinions on qualifications grounds, two opinions on reliability grounds, and the remainder of the challenges arise under Fed. R. Evid. 401-403. None of the challenges has merit.

[1] Although Plaintiffs' Motion indicated that its Exhibit A contained a list of cases to which the motion would apply, as required by the Court's prior orders, no such exhibit was attached.

Dr. Johnson's testimony is admissible. He is qualified to offer his opinions and has applied the proper methodology to arrive at his opinions. Dr. Johnson's opinions are relevant to the facts at issue in this litigation. Accordingly, Dr. Johnson's testimony complies with the standards set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993) and the Federal Rules of Evidence and should be admitted.

## ARGUMENT AND AUTHORITIES

### I. Standard for admissibility of expert opinion testimony

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D. W. Va. 2014).

### II. Dr. Johnson Is Imminently Qualified to Offer His Opinions in This Matter

Dr. Johnson is unquestionably an expert in the field of urogynecology, stress urinary incontinence ("SUI"), and the surgical treatment of SUI. Dr. Johnson is a board-certified obstetrician-gynecologist with more than thirty years of education, training, and experience. He is currently the Vice Chairman of OB/GYN, Division Director of Urogynecology and Reconstructive Surgery at University of Maryland Medical Center. Dr. Johnson has extensive experience in treating SUI, has implanted more than 750 polypropylene midurethral slings, and has treated dozens of patients for sling-related complications. He is also a well-known clinical researcher in this area, who was a co-principle investigator and a founding member of the Urinary Incontinence Treatment Network ("UITN"), which was established by the National Institute of Diabetes, Digestive and Kidney Disease. The UITN conducted several large, prospective, randomized, surgical trials of fascial slings, Burch colposuspension, and midurethral synthetic slings (including TVT and TVT-O) under the direction of the National Institute of Health from 2000 to 2010. *See generally* Curriculum Vitae of Harry Wallace Johnson, Jr., M.D.

("Johnson CV") [Dkt. 3273-2]; General Expert Report of Dr. Harry Johnson, Jr., M.D. Regarding TVT ("Johnson Report") [Dkt. 3273-1].

At the outset of their Brief, Plaintiffs make the generic statement that certain opinions of Dr. Johnson are "beyond the field of his expertise." Pls.' Br. [Dkt. 3274] at 1. Plaintiffs do not contest Dr. Johnson's credentials to offer the overwhelming majority of his opinions, however. Buried within Plaintiffs' Brief are the two discrete points on which they contend Dr. Johnson is unqualified to opine. First, they argue that Dr. Johnson lacks the qualifications to opine on the FDA's 510(k) clearance process. Second, Plaintiffs contend that Dr. Johnson is unqualified to discuss the adequacy of the TVT Instructions for Use ("IFU"). The first contention is a red-herring; the second is without merit.

**A. Dr. Johnson does not intend to opine on the FDA 510(k) clearance process**

Dr. Johnson's report contains a single reference to the FDA 510(k) clearance of TVT. It reads: "TVT was introduced in the United States by Ethicon in 1998 after receiving 510K clearance by the FDA." Johnson Report [Dkt. 3273-1] at 11. This is not an opinion; this is a statement of fact. Dr. Johnson's qualifications do not come into play to support this factual assertion. Plaintiffs' attempt to contest this fact statement under the guise of a qualifications argument is a red-herring—a futile attempt to discredit an otherwise incontestable expert.

Plaintiffs' argument regarding Dr. Johnson's 510(k) clearance fact statement should have been raised as a motion *in limine*, not a *Daubert* challenge. Ethicon recognizes the Court's prior order excluding evidence regarding the FDA's 510(k) clearance process as irrelevant. Without further belaboring prior briefing, Ethicon respectfully re-submits that the 510(k) process is relevant and evidence of TVT's 510(k) clearance—including Dr. Johnson's statement of fact—should be admitted.

**B. Dr. Johnson is qualified to opine that the Defendants' IFUs, when read by the intended user possessing the common knowledge of the profession, sufficiently inform of the relevant risks**

Plaintiffs claim that "nowhere in Dr. Johnson's expert report or curriculum vitae does he list any experience or credentials that render him qualified to opine on the adequacy of Defendants' IFU." Pls.' Br. [Dkt. 3274] at 11. This statement overgeneralizes Dr. Johnson's testimony. Ethicon concedes that Dr. Johnson is not a regulatory expert and does not intend to opine regarding the regulatory adequacy of the IFU.

Instead, Dr. Johnson's testimony addresses the central issue in Plaintiffs' failure-to-warn claim: whether the risks identified in the IFU when read by the intended user possessing the common knowledge of a pelvic floor surgeon are sufficient to inform the user of the relevant risks from a clinical perspective. This testimony is the proper province of an expert urogynecologist with extensive education, training and experience, such as Dr. Johnson. Indeed, only an expert in the field could offer this critical testimony.

Ethicon has no duty to warn of risks commonly known to the intended users of the device.[2] The common knowledge of intended users is thus a necessary fact that must be considered in judging the adequacy of the warnings in the IFU package insert. Dr. Johnson is well-qualified to testify as to what the intended users commonly knew, and to compare that to both the risks of the surgery and the list of adverse events in the IFU. Plaintiffs' criticism fails to take into account the

[2] See *infra*, section III(B) discussing in detail the legal standard for a failure to warn claim; *See, e.g., Brooks v. Medtronic*, 750 F.2d 1227, 1230 (4th Cir. 1984) (duty to warn of characteristics "not well known to the medical community"); *Huskey v. Ethicon, Inc.* No. 2:12-cv-05201, 2015 W.L. 4944339 at *7 (S.D.W.Va. Aug. 19, 2015 (no duty to warn of "risks already known to the medical community"); Restatement (Third) of Torts: Product Liability §2 cmt. j (1998); Restatement (Second) of the Law of Torts §402A cmt. j; American Law of Product Liability 3d § 32:69 (2016); *Willis v. Raymark Indus., Inc.*, 905 F.2d 793, 797 (4th Cir. 1990). In fact, 21 CFR § 801.109(c) states there is no duty to warn if "the article is a device for which the hazards, warnings and other information are commonly known to practitioners licensed by law to use the device."

critical role of users' common knowledge, and so it is grounded in a legal error that renders it mistaken at every turn.

Dr. Johnson knows the risks of implanting mesh and whether those risks appear on the IFU. Consistent with the Court's prior rulings, as an imminently qualified obstetrician-gynecologist board certified in Female Pelvic Medicine and Reconstructive Surgery, Dr. Johnson "may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU." *In re: Ethicon,* 2016 WL 4582231, at *3. Dr. Johnson's report details his extensive experience with the TVT and TVT-O devices, including particular risks and complications he has experienced and researched. Pl's Ex. A, Expert Report at 1-5. His extensive clinical experience with the products in issue is supplemented by a thorough review of the relevant literature and education he has provided to others. *Id., passim*; Ex. D, Reliance List.

Dr. Johnson will testify that the complications Plaintiffs contend were wrongly omitted from the IFUs: (a) are risks that a pelvic surgeon would already know, and therefore, need not be warned about; (b) are not genuine complications; or (c) are not attributable to the device. He is fully competent to give this testimony.

Dr. Johnson, as an experienced clinician, is well qualified to testify about complications that are well-known and obvious to pelvic floor surgeons performing those types of procedures. Dr. Johnson relies on not only his extensive experience performing pelvic floor surgery, but also his thorough review of medical literature; his direct involvement in studies comparing the Burch procedure, fascial slings, and TVT devices; his years of academic involvement; and his supervisory experience overseeing residents and medical students in this field. *See* Pl's Ex. B, Curriculum Vitae of Dr. Harry Johnson at 2 (detailing numerous academic positions held from 1992-present); *id.* at 4 (detailing supervisory and lecture experience related to gynecology and gynecologic

surgery dating from 1993 through present); *id.* at 7-9 (detailing invited speeches and presentations, many relating to surgical management of incontinence and related surgical injuries); Plf's Ex. A, Expert Report at 3-5 (detailing presentation, training and teaching experience); Ex. A, hereto, Johnson 7/14/16 Dep at 22-25, 46-53, 62-63 (detailing involvement in Urinary Incontinence Treatment Network's (UITN) studies beginning 2000 forward, comparing efficacy and adverse events of Burch procedure, other facial slings, TVT and TVT-O). Dr. Johnson is certainly well-qualified to testify that the risks of non-mesh pelvic floor surgery are similar in kind to those of mesh surgery, and are common knowledge to any surgeon who does either. Pl's Ex. A, Expert Report at 29-33 (listing risks such as pain, dyspareunia, and bleeding, and noting "[t]hese general surgical risks are commonly known to experienced pelvic floor surgeons who are the intended users of the IFU.").

Moreover, the law is clear that experts may testify as to the knowledge common within a profession or community. *See Flannery v. Bauermeister*, No. CIV.A. 06-399S, 2008 WL 77723, at *2 (D.R.I. Jan. 4, 2008) (granting summary judgment in part based on testimony from the experts as to what "is known within the correctional medical community"); *Cruz-Vargas v. R.J. Reynolds Tobacco Co.*, 348 F.3d 271, 277 (1st Cir. 2003) (allowing expert testimony of "common knowledge"); *U.S. v. Articles of Device*, 426 F.Supp. 366 (W.D.Pa. 1977) (FDA offered affidavit on common knowledge in misbranding case). Thus, the IFU supplements all the other sources of a surgeon's knowledge.

Dr. Johnson is also qualified to testify that certain allegedly omitted risks are not genuine risks of the surgery or are not attributable to the device. Dr. Johnson's report shows that his opinions are based on his extensive clinical experience and research, *as well as* his thorough critique of scientific literature. *See, e.g.*, Pl's Ex. A, Expert Report at 23-25, 27-29, 34-36

(explaining why he disputes that mesh causes various conditions, such as damage from particle loss or contraction, or degradation). *See also Huskey*, 29 F. Supp. 3d at 734-35 (allowing Dr. Johnson to testify about evidence of absence because his opinions were also based on medical literature); *Carlson*, 2015 WL 1931311 at *12.[3]

For these reasons, Ethicon respectfully requests that this Court not only continue to rule that Dr. Johnson is qualified to testify both regarding the surgical risks as disclosed in the IFU and the common knowledge of physicians, but may also state that the IFU is clinically sufficient to inform the intended user of the relevant risks in light of that common knowledge.

## III. Dr. Johnson's Methodology Is Reliable

As with Plaintiffs' limited qualifications-challenge, Plaintiffs do not contest Dr. Johnson's methodology for the vast majority of his opinions. In fact, Plaintiffs challenge only two of Dr. Johnson's opinions on purported reliability grounds: (1) Dr. Johnson's opinion that the TVT is the "gold standard" for SUI surgery; and (2) Dr. Johnson's opinion that the IFU adequately warns of the associated risks. Both reliability challenges are without merit.

### A. Dr. Johnson applies a reliable methodology to determine that TVT is the "gold standard" and Plaintiffs cite nothing to counter this conclusion

Plaintiffs' challenge to Dr. Johnson's "gold standard" opinion is legally unsupported. Plaintiffs appear to take the position that if an expert uses the words "I think so" in his deposition, then his opinion is unreliable. *See* Pls.' Br. at 8-9. Specifically, Plaintiffs contend that when Dr. Johnson used the phrase "I think so" he "equivocated" on his opinion that TVT is the

[3] While this Court has observed that "[a]bsence of evidence is not evidence of absence," *Tyree*, 54 F. Supp. 3d at 583-84, the observation only holds true where a cursory inquiry of the evidence has been made. For instance, if a physician is relying merely on his own experience to opine that a particular risk does not exist, the methodology may be flawed. However, where, as here, a physician examines the evidence outside of his own experience, such as by critiquing the medical literature and studying the conclusions of medical organizations, then the physician's opinions have a reliable basis. If there is no reliable evidence of risk as determined by a detailed review of appropriate sources, there is no obligation to include the risk in the IFU warnings.

gold standard. Plaintiffs' premise is based on verbal phrase-parsing effectuated by truncating Dr. Johnson's testimony. In their Brief, Plaintiffs quote only a snippet of Dr. Johnson's testimony. Pls.' Br. [Dkt. 3274] at 8-9. What Plaintiffs exclude is the relevant testimony immediately following the quoted testimony. In full, Dr. Johnson's testimony on the subject reads:

> **Q. … ["T]he TVT procedure has been rapidly accepted and has become the gold standard for treatment of stress urinary incontinence."**
> **Do you see that sentence?**
>
> **A. I do.**
>
> Q. What does gold standard mean?
>
> A. That would be the most commonly performed procedure for treatment of urinary incontinence or the most widely accepted common treatment.
>
> Q. So if there's treatment for SUI -- and in this case, we're referring to the TVT treatment -- if it's the most common or the most widely accepted, then it's the gold standard?
>
> A. It's the most commonly performed procedure in the world, TVT is.
>
> Q. So that makes it the gold standard?
>
> A. I think so.
>
> **Q. Okay. Any other factors that would make a procedure gold standard or not?**
>
> **A. Well, I think this procedure was looked at where they compared it to – and this would include TVT, TVT-O procedures. So they looked at –**
>
> **Q. I'm only interested, just so you know, in the TVT procedure.**
>
> **A. Right.**
>
> **Q. So --**

**A. I mean, but we just talked about that the TOMUS compared the two and they were relatively equivalent. That's the only reason I bring that up.**

**Q. I understand.**

**A. But I understand.**

**So it's the most commonly performed procedure for stress incontinence in the world. It's been approved by -- or endorsed by all professional organizations that look at pelvic floor treatment. It's the most studied procedure probably in history regarding treatment of urinary incontinence.**

Ex. A, Johnson 7/14/16 Dep. 63:24-65:14 (emphasis added to portions omitted from Pl's brief).[4]

Dr. Johnson defined the term "gold standard," explained how TVT satisfied the term, and supports his explanation with reference to the literature. Plaintiffs do not argue that Dr. Johnson's basis for determining TVT to be the gold standard is incorrect. They do not contest that the TVT is the most commonly performed procedure for SUI in the. They do not contest that TVT has been endorsed by every professional organization that focuses on pelvic floor treatment. They do not contest that it is the most widely studied treatment in the history of the SUI treatments.

Instead, they truncate his testimony, complain that the words "I think so" constitute an equivocation, and cite no law to support their argument. At bottom, Plaintiffs have done nothing to call into question Dr. Johnson's methodology. Plaintiffs' motion should be denied.

**B. Dr. Johnson's IFU opinions are reliable**

Plaintiffs argue that Dr. Johnson's opinion that the TVT IFU sufficiently warned physicians of the risks associated with the product is unreliable because Dr. Johnson testified that

[4] Plaintiffs' inadvertently supplied the Court with one of the case-specific deposition transcripts of Dr. Johnson, instead of the general deposition of Dr. Johnson. Accordingly, the quoted language above is not found in Plaintiffs' Exhibit C [Dkt. 3273-3]. Defendants have attached the correct general-causation deposition hereto.

it would have been possible to list additional adverse events in the IFU. Plaintiffs cite to nothing for the proposition that an adequate IFU must contain all feasible warnings. Indeed, Plaintiffs' argument demonstrates their fundamental misunderstanding of the law on this critical point.

Plaintiffs' entire line of questioning on the subject of additional adverse events consisted of a series of inquiries asking Dr. Johnson if certain additional adverse events "could" or "can" be listed, not whether the additional adverse events "should" be listed to fully inform the surgeon. Contrary to Plaintiffs' argument, the fact that some additional adverse event "could" be included does not render the IFU inadequate.

Plaintiffs' continually omit analysis of the end users' common knowledge from their arguments, proceeding under the fallacy that all risks (whether commonly known or not) must be contained in the IFU. Based on this legal misunderstanding, Plaintiffs spend pages of their brief arguing that Dr. Johnson's testimony regarding the clinical sufficiency of the IFU is contradictory (and thus unreliable) because Dr. Johnson admits that certain (known) risks are not contained in the IFU. Pl's Brief at 10-11.

Yet, neither the law nor the practice of medicine requires device manufacturers to list every possible adverse event and certainly does not require manufacturers to list adverse events that are commonly known by the implanting surgeons. Accurately characterized, Dr. Johnson opines that the risks disclosed in the IFU, when read by a surgeon possessing the common knowledge of his profession, sufficiently inform the user of the relevant known risks.

Under applicable law, a device manufacturer's duty to warn of adverse events does not include a duty to warn of risks commonly known to the surgeons who use the device. Therefore, an IFU does *not* need to list every known risk associated with a product in order to adequately warn the treating physician As stated generally in the RESTATEMENT (THIRD) OF TORTS:

PRODUCT LIABILITY § 2, cmt. j, a product seller "is not subject to liability for failing to warn or instruct regarding risks and risk-avoidance measures that should be obvious to, or generally known by, foreseeable product users." *See also* RESTATEMENT (SECOND) OF THE LAW OF TORTS §§ 388(b), 402A, cmt. j; *Roney v. Gencorp*, 654 F. Supp. 2d 501 (S.D. W. Va. 2009) (adopting "sophisticated user" defense in § 388).

The test is an objective test that depends on the knowledge of foreseeable users generally, and not on the knowledge of the person whose use is at issue in the particular case. *Parker v. Brush Wellman, Inc.*, Civ. A. No. 1:04-CV-606-RWS, 2010 U.S. Dist. LEXIS 97702, at *28-29 (N.D. Ga. Sept. 17, 2010) ("The user's knowledge should be viewed from 'an objective point of view, as opposed to subjective, since the user's perceptions are irrelevant.' (citing *Morris v. Clark Equip. Co.*, 904 F. Supp. 1379, 1383 (M.D. Ga. 1995).

This limitation on the duty to warn is recognized in medical cases as well. There is no duty to warn of risks commonly known to implanting surgeons. *See Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1230 (4th Cir. 1984) (duty to warn only of dangers "not well known to the medical community."); . *Huskey v. Ethicon, Inc.* No. 2:12-cv-05201, 2015 W.L. 4944339 at *7 (S.D.W.Va. Aug. 19, 2015 (no duty to warn of "risks already known to the medical community"); *see also Wright ex rel. Trust Co. of Kansas v. Abbot Laboratories, Inc.*, 259 F.3d 1226, 1234 (10th Cir. 2001) (drug company had no duty to warn hospital of the danger of stocking different concentrations of saline solution in the same place); *Brown v. Drake-Willock Intern. Ltd.*, 530 N.W. 2d 510, 516 (Mich. App. 1995) (physician was sophisticated user of dialysis machine).[5]

[5] In fact, the FDA device regulations say that information may be omitted from labeling: "if, but only if, the article is a device for which directions, hazards, warnings and other information are commonly known to practitioners licensed by law to use the device." 21 C.F.R. §801.109(c) (emphasis added).

The IFUs at issue here restrict the class of surgeons who are to use the devices. They contemplate that users will be familiar with traditional surgical techniques used to treat stress urinary incontinence. The TVT IFU says the device "should be used only by physicians trained in the surgical treatment of [SUI] and specifically in implanting the TVT device." Ex. B, attached hereto, TVT IFU (ETH.MESH.00875481).

So a central question with respect to Plaintiffs' failure to warn claim is what "hazards" were "commonly known" to surgeons familiar with traditional non-mesh SUI surgery and mesh surgery before TVT was introduced. Ethicon had no duty to warn of adverse events "commonly known" to those surgeons. Its duty was to warn of adverse events that were unique to the new devices, or, at the very least, unique to the use of mesh.

As explained by Dr. Johnson in his depositions, although certain IFUs do not specifically identify the risk of urinary tract infections and dyspareunia, these risks are common risks of any pelvic floor surgery, are not unique to TVT, and are commonly known risks among practitioners. *See* Ex. A, Johnson 7/14/16 Dep. 75:2-78:4. Accordingly, contrary to Plaintiffs' argument, omission of these commonly known risks from the IFU label would not render the label inadequate.

The crux of Plaintiffs' argument about the reliability of Dr. Johnson's IFU testimony is that they contend Ethicon could have exceeded this standard and warned of non-unique risks that are commonly known to surgeons. The standard for the adequacy of warnings contained in an IFU is set by the well-settled law set forth above. Any criticism of Dr. Johnson's methodology based on his testimony that it was possible for Ethicon to exceed the applicable standard is without merit. Dr. Johnson's opinions and testimony regarding whether the warnings contained in the IFU, when combined with common knowledge of the end user, sufficiently informed the

intended user of the product risks is consistent with the governing legal standard, is based on extensive experience and thorough review of the medical literature, and should be admitted.

## IV. Plaintiffs' Remaining Substantive Objections Turn on Questions of Relevance

Plaintiffs also rely on Fed. R. Evid. 401, 402, and 403 to attack five discrete opinions held by Dr. Johnson. Specifically, Plaintiffs contend: (1) that Dr. Johnson's opinions regarding the TVT-O are irrelevant; (2) that his opinions regarding the SISTEr studies are irrelevant and present the risk of jury confusion; (3) that his opinions regarding the 2015 IFU are irrelevant; (4) that his opinion that TVT is the "gold standard" will confuse or mislead the jury; and (5) that Dr. Johnson's reliance on the Cochrane review will confuse or mislead the jury. Each of these topics is relevant and admissible, and Plaintiffs' Rule 401-403 objections should be overruled.

### A. Dr. Johnson's opinions regarding the TVT-O are relevant and admissible

Copying verbatim from their Motion to Exclude Dr. Johnson filed in *Mullins, et al. v. Ethicon, Inc.*, No. 2:12-CV-02952, Plaintiffs argue that Dr. Johnson's opinions regarding TVT-O are irrelevant to "these consolidated cases", which "involve Defendants' TVT product, not TVT-O." While that description may have been true in the *Mullins* consolidated cases, it is not true in Wave 3. Wave 3 plaintiff, Christina Webb, was implanted with Defendants' TVT-O product and complains of related alleged injuries. *See Christine Webb and Joseph Webb v. Ethicon, Inc. et al*. Case No. 2:12-CV-03136. Plaintiffs' motion should be denied on this ground alone.

Moreover, even in cases where the plaintiff was implanted with the TVT product, certain opinions regarding the safety and efficacy of TVT-O are still relevant.

As the Court is well aware, TVT and TVT-O are made from the same Prolene mesh. One of Plaintiffs' theories of defect is that Prolene degrades in vivo and causes pain. Thus, while it may be true that some aspects of the TVT-O placement would not be relevant to these TVT cases

(specifically the placement of the sling via the obturator approach), it is an overstatement to claim that none of Dr. Johnson's TVT-O opinions are relevant. So long as Plaintiffs attempt to attack the Prolene mesh on biocompatibility, Dr. Johnson's opinions regarding the low adverse event rate associated with TVT-O and his opinions regarding the safety and efficacy of TVT-O are relevant to Wave 3 cases involving both TVT and TVT-O.

**B. Dr. Johnson's opinions regarding the SISTEr and E-SISTEr Trials are relevant and admissible**

The SISTEr and E-SISTEr trials compared the Burch colposuspension to fascia sling surgeries. These trials revealed high adverse event rates for both procedures. Plaintiffs contend that Dr. Johnson's opinions regarding these trials are irrelevant and that they do not go to the issue of whether the TVT is safe and effective. Plaintiffs are mistaken.

As an initial matter, Plaintiffs' experts contend that the Burch colposuspension and/or fascia sling surgeries are safer alternatives to and equally efficacious as the TVT. *See, e.g.,* Ex. C, Report of Bruce Rosenzweig, M.D. at 9-10 ("Although the Burch procedure may take longer and require a very small hospitalization, it is a much safer procedure than synthetic slings because life-altering long-term complications do not occur with Burch like they do with synthetic slings, including chronic debilitating pain, chronic sexual dysfunction and dyspareunia, erosions, multiple surgeries to remove mesh, emotional issues related to sexual dysfunction and many others as discussed throughout this report. Furthermore, if complications do occur following a Burch procedure, they are very rarely long-term and much easier to treat."); *see also id.* at 10-11 (discussing the purported advantages of a fascia sling); *id.* at 94 ("This is especially true given that traditional surgeries like the Burch and pubovaginal slings are not associated with the frequency or extent of these life changing complications. The efficacy of the TVT is equivalent to the traditional surgeries like the Burch. Traditional surgeries are not associated with

TVT mesh based complications like contraction and erosion, however, with clinically significant erosion. And, further, although traditional surgeries can cause symptoms such as pain following surgery, including dyspareunia, the risk, duration, extent and severity of chronic pain including dyspareunia following the TVT is much greater than with traditional surgeries, and of course those surgeries do not result in the often untreatable complications and symptoms that result from the TVT mesh.").[6]

Accordingly, Plaintiffs have made the safety and efficacy Burch colposuspension and/or fascia sling surgeries a material issue in this trial, and Dr. Johnson's opinions regarding the safety and efficacy of these alternative procedures are relevant to rebut Plaintiffs' experts.

Second, if Plaintiffs are allowed to introduce evidence regarding the Burch colposuspension and/or fascia sling surgery, safety and efficacy data related to these procedures do inform the question of whether the TVT is safe and effective . SUI can be a debilitating and life-altering condition for many women; often surgical intervention is needed to treat the condition. All surgeries present the risk of adverse events. The jury is entitled to have information regarding the adverse event rates associated with other pelvic floor surgeries to determine whether the risks outweigh the benefits of the device. Likewise, the jury should be able to compare the risks associated with other SUI surgeries to the risks associated with TVT. Similarly, the jury should be allowed to compare the effectiveness of those alternative procedures to the effectiveness of TVT. The jury should not be left to assess the safety and efficacy of TVT in an artificial vacuum.

[6] Defendants have consistently argued that the Burch and other fascia sling surgeries are different surgical procedures, not alternative designs of TVT or TVT-O. Thus data related to such procedures cannot satisfy Plaintiffs' burden to establish a safer alternative design, to the extent such requirement exists under the applicable state law.

Plaintiffs also argue that Dr. Johnson's opinions regarding the SISTEr and E-SISTEr trials present the possibility of jury confusion. Specifically, Plaintiffs contend that this information "will confuse the jury insofar as they may infer … that high adverse event rates with prior non-synthetic procedures logically lead to the assumption that Defendants' TVT product is safe." Pls.' Br. [Dkt. 3724] at 12. First, Plaintiffs cite nothing to demonstrate that this would be an unfair inference for the jury to make. If the TVT surgery is safer than the alternative non-mesh surgeries, then it would be fair for the jury to infer that the product is safer than they are..

Second, even if this potential inference were somehow unfair, Plaintiffs merely speculate that the jury may make this analytical leap. As discussed above, the adverse events rates of the alternative procedures is probative to the issue of whether TVT is safe and effective. That probative value is not substantially outweighed by Plaintiffs' speculation about what the jury may or may not do with that information.

### C. Dr. Johnson's opinions regarding the 2015 TVT IFU are relevant and admissible

Without citing or discussing the substance of his opinions, Plaintiffs argue that Dr. Johnson's opinions regarding the 2015 TVT IFU are irrelevant, based solely on a temporal argument—i.e., Plaintiffs devices were implanted before 2015, so any evidence regarding the 2015 IFU must be irrelevant.

As discussed above, Plaintiffs argue that the TVT IFU was deficient because it failed to include express warnings regarding commonly known risks of pelvic floor surgery, including recurrent urinary tract infections and dyspareunia. In 2015, Ethicon added several adverse events to its IFU, including statements about infections and dyspareunia. Dr. Johnson's opinion about the 2015 TVT IFU is that these additional adverse events are "general surgical risks of all pelvic floor surgeries, including any surgery to treat SUI. These general surgical risks are commonly

known to experienced pelvic floor surgeons who are the intended users of the IFU. Only mesh erosion or exposure is unique to TVT…." *See* Pl's Ex. A, Johnson Report [Dkt. 3273-1] at 29.

The fact that the risks were added to the IFU in 2015 is not relevant to the cases in Wave 3 which all involve plaintiffs whose implants predated the change. However, Dr. Johnson's opinion—that the specific risks added to the 2015 IFU are "general surgical risks of all pelvic floor surgeries," "commonly known," and non-unique—is relevant and goes to the heart of Plaintiffs' failure to warn claims.

Ethicon agrees with Plaintiffs on the limited point that the fact that the risks were added to the IFU in 2015 should not be admitted at the trial of this matter. Ethicon moved *in limine* in Wave 1 to exclude the 2015 revisions to the IFU as a subsequent remedial measure and will do so when appropriate in Wave 3. *See* Defs.' Mem. in Support of Omnibus Mot. *in Limine* [Dkt. 940] at 1-4. Contrary to their arguments here, Plaintiffs oppose that motion *in limine* and argue that information regarding the 2015 revisions is admissible. *See* Pls.' Resp. to Defs.' Mots. in Limine [Dkt. 1208] at 3-5. If the Court, or any remand court, denies Ethicon's Motion *in Limine* to exclude evidence of the 2015 revisions, Dr. Johnson's opinions are admissible for the purpose of rebutting any implication by Plaintiffs that the revisions constitute evidence of inadequacy.

**D. Dr. Johnson's opinion regarding TVT being the "gold standard" is not substantially outweighed by the danger of confusing or misleading the jury**

Plaintiffs attempt to re-litigate an issue that has already been decided by this Court:

> The plaintiffs argue that Ethicon should be prohibited from presenting evidence or argument that the TVT-O is the "gold standard" for the treatment of SUI. The plaintiffs believe that this term should be excluded as irrelevant, overly prejudicial, and misleading because it is imprecise and different experts disagree about what exactly it means. I have already addressed this issue with regard to Ethicon's other product, the TVT. *See In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-cv-4301, 2014 U.S. Dist. LEXIS 14971, 2014 WL 505234, at *3 (S.D. W. Va. Feb. 5, 2014). Whether the TVT-O is regarded as the "gold standard" is

> highly probative: it goes to the very essence of whether the TVT-O is unreasonably dangerous and whether there existed safer alternative designs. *See Mikolajczyk v. Ford Motor Co.*, 231 Ill. 2d 516, 901 N.E.2d 329, 347, 327 Ill. Dec. 1 (Ill. 2008) ("[T]he existence of a feasible alternative design and the balancing of risks and benefits are relevant considerations in a strict product liability design defect case[.]"). If the plaintiffs believe that "gold standard" is imprecise, inaccurate, or confusing, they may vigorously cross-examine witnesses. Accordingly, this motion in limine is DENIED.

*Huskey v. Ethicon, Inc.*, Civ. A. No. 2:12-cv-05201, 2014 U.S. Dist. LEXIS 107887, at *5-6 (S.D. W. Va. Aug. 6, 2014); *see also Lewis*, Civ. A. No. 2:12-cv-4301, 2014 U.S. Dist. LEXIS 14971, at *8-9 (holding same in relation to TVT).

This Court again should overrule this objection. "If the plaintiffs believe that 'gold standard' is imprecise, inaccurate, or confusing, they may vigorously cross-examine witnesses." *Huskey*, 2014 U.S. Dist. LEXIS 107887, at *6.

**E. Dr. Johnson's opinions that rely on the 2015 Cochrane review are probative and do not present a danger of misleading the jury**

Plaintiffs' challenge regarding Dr. Johnson's opinions that are based upon the 2015 Cochrane review is an issue for cross-examination. Plaintiffs argue that the Cochrane review has certain limitations and that Dr. Johnson is not giving those limitations proper consideration. The entirety of Plaintiffs' Rule 403 argument is that "Dr. Johnson's statement that the Review is one of the 'highest level[s] of scientific evidence' is misleading as the Review is premised upon 'moderate' evidence." Pls.' Br. [Dkt. 3274] at 13. This is an argument about the weight, not admissibility of Dr. Johnson's testimony. If Plaintiffs believe the Cochrane review does not represent the "highest level of scientific evidence" they are free to take-up the issue on cross-examination. But Dr. Johnson's opinion should not be excluded just because Plaintiffs disagree with the quality of the evidence upon which he relies.

## V. Plaintiffs' Argument that Dr. Johnson Failed to State the Bases of His Opinions Is Erroneous

Plaintiffs argue that any time Dr. Johnson provided an opinion without a footnote citation to the specific document upon which he relied, the opinion should be excluded pursuant to Fed. R. Civ. P. 26. This argument is legally unsupported.

As an initial matter, Plaintiffs cite to only one opinion that they claim to be an "uncited opinion," that "Up to 50% of women may improve enough to forego surgical treatment initially, however >90% of these patients remain incontinent and > 60% may subsequently seek surgical management." Pls.' Br. [Dkt. 3274] at 5 (quoting Johnson Report at 5). Other than this innocuous statement regarding the percent of women who experience SUI, Plaintiffs point to no other opinions with which they take issue.

Second, even a cursory review of Dr. Johnson's Report reveals that all substantive discussions regarding the safety and efficacy of TVT, the safety and efficacy of alternative procedures, and the adequacy of the IFU provide citations to the authorities upon which those opinions are based.

Third, Plaintiffs assume that this one "uncited opinion" is derived from a written document instead of Dr. Johnson's decades-long experience. As Dr. Johnson stated at the outset of his Report, his opinions "are based on [his] education, training, knowledge, personal and clinical experience, publications, lectures, teaching, review of the literature, interactions with colleagues, and a list of materials [he has] reviewed." Pl's Ex. A, Johnson Report at 3.

Fourth, Plaintiffs argue that they "have no way of determining the basis for such opinions, let alone an ability to prepare to rebut these opinions at trial." Pls.' Br. [Dkt. 3274] at 5. Presumably, Plaintiffs mean they have no way of determining the basis for these opinions other than asking Dr. Johnson for the bases of the opinions when they had him under oath on July 14,

2016. In fact, Plaintiffs specifically deposed Dr. Johnson on these exact sentences in his deposition. Yet Plaintiffs did not ask Dr. Johnson to identify the source from which this opinion was derived. *See* Ex. A, Johnson 7/14/16 Dep. 30:19-31:18. Accordingly, Plaintiffs' complaint regarding the lack of citation is disingenuous.

Plaintiffs' argument is not saved by their further complaints regarding Dr. Johnson's allegedly over-inclusive reliance list. As Dr. Johnson explained, his reliance list properly contained not only materials he specifically relied upon (and expressly cited in his report), but also all materials he was provided by Defendants for consideration in preparing his report. Ex. A, Johnson 7/14/16 Dep. 7:13-12:14. While Dr. Johnson considered these materials, he did not analyze or rely on all of the materials because, based on his extensive experience and independent research, they were not necessary to support his opinion. *Id.* If Dr. Johnson had failed to list materials that he had been provided by Defendants, Plaintiffs would be complaining about that omission. Instead, Dr. Johnson listed all materials provided to him or that he independently relied upon to prepare his reliance list. Furthermore, his report contains specific citations to individual sources that support specific opinions.

Dr. Johnson's Report and Reliance List satisfy both the spirit and the letter of Rule 26. Dr. Johnson provided a detailed statement of his opinions, listed the universe of documents from which his opinions were derived, and routinely provided a specific citation linking his opinions to specific documents. If any of this was deemed insufficient by Plaintiffs to fairly apprise them of Dr. Johnson's opinions, the time to resolve the issue was during Dr. Johnson's discovery deposition. Plaintiffs chose not to do so. Nothing in the Rules of Civil Procedure mandates a greater level of detail than was provided by Dr. Johnson. Accordingly, Plaintiffs' complaints about "uncited opinions" are unfounded and should be excluded.

## CONCLUSION

For all of these reasons, Plaintiffs' motion to exclude the opinion testimony of Harry Johnson, M.D. should be denied. Ethicon prays for any additional or further relief to which it may be entitled.

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**CERTIFICATE OF SERVICE**

I, Christy D. Jones, certify that on this date, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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